DECISIONS OF THE PARTIES TO THE MONTREAL PROTOCOL

B.1 Decision IV/25. Essential uses

1. To apply the following criteria and procedure in assessing an essential use for the purposes of control measures in Article 2 of the Protocol:

(a) that a use of a controlled substance should qualify as "essential" only if:
   (i) it is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and
   (ii) there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;

(b) that production and consumption, if any, of a controlled substance for essential uses should be permitted only if
   (i) all economically feasible steps have been taken to minimise the essential use and any associated emission of the controlled substance; and
   (ii) the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries’ need for controlled substances;

(c) that production, if any, for essential use, will be in addition to production to supply the basic domestic needs of the Parties operating under paragraph I of Article 5 of the Protocol prior to the phase out of the controlled substances in those countries;

2. To request each of the Parties to nominate, in accordance with the criteria approved in paragraph I (a) of the present decision, any use it considers "essential", to the Secretariat at least six months for halons and nine months for other substances prior to each Meeting of the Parties that is to decide on this issue;

3. To request the Technology and Economic Assessment Panel and its Technical and Economic Options Committee to develop, in accordance with the criteria in paragraphs I (a) and I (b) of the present decision, recommendations on the nominations, after consultations with experts as necessary, regarding:

(a) the essential use (substance, quantity, quality, expected duration of essential use, duration of production or import necessary to meet such essential use);

(b) economically feasible use and emission controls for the proposed essential use;

(c) sources of already produced controlled substances for the proposed essential use (quantity, quality, timing); and

(d) steps necessary to ensure that alternatives and substitutes are available as soon as possible for the proposed essential use;

4. To request the Technology and Economic Assessment Panel, while making its recommendations to take into account the environmental acceptability, health effects, economic feasibility, availability, and regulatory status of alternatives and substitutes;
5. To request the Technology and Economic Assessment Panel to submit its report, through the Secretariat, at least three months before the Meeting of the Parties in which a decision is to be taken. The subsequent reports will also consider which previously qualified essential uses should no longer qualify as essential;

6. To request the Open ended Working Group of the Parties to consider the report of the Technology and Economic Assessment Panel and make its recommendations to the Fifth Meeting of the Parties for halons and at the Sixth Meeting for all other substances for which an essential use is proposed;

7. That essential use controls will not be applicable to Parties operating under paragraph I of Article 5 of the Protocol until the phase out dates applicable to those Parties.

B.2 Decision V/14. Essential uses of halons

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Halons Technical Options Committee pursuant to Decision IV/25 of the Fourth Meeting of the Parties;

2. That no level of production or consumption is necessary to satisfy essential uses of halon in Parties not operating under paragraph I of Article 5 of the Protocol, for the year 1994 since there are technically and economically feasible alternatives and substitutes for most applications, and since halon is available in sufficient quantity and quality from existing stocks of banked and recycled halon.

B.3 Decision V/8. Timetable for the submission and consideration of essential use nominations

1. To request the Parties to submit their nominations for each production and consumption exemption for substances other than halon for 1996 in accordance with Decision IV/25, with the presumption that the Meeting of the Parties will be held on 1 September;

2. To modify the timetables in Decision IV/25 for nominations for halon production and consumption exemptions for 1995 and subsequent years, and for nominations for production and consumption exemptions for substances other than halon for 1997 and subsequent years as follows: to set 1 January of each year as the last date for nominations for decisions taken in that year for any subsequent year;

3. To request the Technology and Economic Assessment Panel and its relevant Technical Options Committees to develop recommendations on the nominations and submit their report through the Secretariat by 31 March of that year;

4. To request the Open ended Working Group of the Parties to consider the report of the Technology and Economic Assessment Panel and make its recommendations to the subsequent meeting of the Parties;

5. To request the Technology and Economic Assessment Panel to assemble and distribute a handbook on essential uses nominations including copies of relevant decisions, nomination instructions, summaries of past recommendations, and copies of nominations to illustrate possible formats and levels of technical detail.

B.4 Decision VI/8. Essential use nominations for halons for 1995

The Sixth Meeting of the Parties decided in Decision VI/8 that, for the year 1995 no level of production or consumption is necessary to satisfy essential uses of halons in Parties not
operating under paragraph 1 of Article 5 of the Protocol, since there are technically and economically feasible alternatives and substitutes for most applications, and since halons are available in sufficient quantity and quality from existing stocks of banked and recycled halons.

B.5 Decision VI/9. Essential use nominations for controlled substances other than halons for 1996 and beyond

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Technical Options Committees pursuant to Decision IV/25 of the Fourth Meeting of the Parties;

2. That, for 1996 and 1997 for Parties not operating under paragraph 1 of Article 5 of the Protocol, levels of production or consumption necessary to satisfy essential uses of chlorofluorocarbons and 1,1,1-trichloroethane for: (i) metered-dose inhalers (MDIs) for the treatment of asthma, chronic obstructive pulmonary disease (COPD), and for the delivery of leuprolide to the lungs and (ii) the Space Shuttle, are authorised as specified in Annex I to the report of the Sixth Meeting of the Parties, subject to annual review of quantities;

3. That for 1996 and 1997, for Parties not operating under paragraph 1 of Article 5 of the Protocol, production or consumption necessary to satisfy essential uses of ozone-depleting substances for laboratory and analytical uses are authorised as specified in Annex II to the report of the Sixth Meeting of the Parties;

4. That Parties shall endeavour to minimise use and emissions by all practical steps. In the case of metered dose inhalers, these steps include education of physicians and patients about other treatment options and good-faith efforts to eliminate or recapture emissions from filling and testing, consistent with national laws and regulations.

B.6 Decision VII/11. Laboratory and analytical uses

1. To note with appreciation the work done by the Laboratory and Analytical Uses Working Group of the Technology and Economic Assessment Panel;

2. To urge Parties to organise National consultative Committees to review and identify alternatives to laboratory and analytical uses and to encourage the sharing of information concerning alternatives and their wider use;

3. To encourage national standards organisations to identify and review those standards which mandate the use of ozone-depleting substances in order to adopt where possible ODS-free solvents and technologies;

4. To urge Parties to develop an international labelling scheme and encourage its voluntary adoption to stimulate awareness of the issue;

5. To adopt an illustrative list of laboratory uses as specified in Annex IV of the report of the Seventh Meeting of the Parties to facilitate reporting as required by Decision VI/9 of the Sixth Meeting of the Parties;

6. To exclude the following uses from the global essential-use exemption, as they are not exclusive to laboratory and analytical uses and/or alternatives are available:

(a) Refrigeration and air-conditioning equipment used in laboratories, including refrigerated laboratory equipment such as ultra-centrifuges;
(b) Cleaning, reworking, repair, or rebuilding of electronic components or assemblies;

(c) Preservation of publications and archives; and

(d) Sterilisation of materials in a laboratory;

7. To request the Technology and Economic Assessment Panel to evaluate the current status of use of controlled substances and alternatives and report progress on the availability of alternatives to the Ninth Meeting of the Parties and later meetings;

8. To urge Parties operating under Article 2 to provide funding within their countries and on a bilateral basis for Parties operating under Article 5 to undertake research and development and activities aimed at ODS alternatives for laboratory and analytical uses;

9. To agree the controlled substances used for laboratory and analytical purposes shall meet the standards for purity as specified in Decision VI/9.

B.7 Decision IX/17. Essential-use exemption for laboratory and analytical uses of ozone-depleting substances

1. That for 1999, for Parties not operating under paragraph 1 of Article 5 of the Protocol, production and consumption necessary to satisfy essential uses of controlled substances in Annexes A and B of the Protocol only for laboratory and analytical uses, as listed in annex IV to the report of the Seventh Meeting of the Parties, are authorized, subject to the conditions applied to exemption for laboratory and analytical uses as contained in annex II to the report of the Sixth Meeting of the Parties;

2. That data for consumption and production should be reported annually under a global essential-use exemption framework to the Secretariat so that the success of reduction strategies may be monitored;

3. To clarify that essential-use exemptions for laboratory and analytical uses of controlled substances shall continue to exclude the production of products made with or containing such substances.

B.8 Decision X/19. Exemption for laboratory and analytical uses

1. To extend the global laboratory and analytical essential-use exemption until 31 December 2005 under the conditions set out in annex II of the report of the Sixth Meeting of the Parties;

2. To request the Technology and Economic Assessment Panel to report annually on the development and availability of laboratory and analytical procedures that can be performed without using the controlled substances in Annexes A and B of the Protocol;

3. That the Meeting of the Parties shall each year, on the basis of information reported by the Technology and Economic Assessment Panel in accordance with paragraph 2 above, decide on any uses of controlled substances which should no longer be eligible under the exemption for laboratory and analytical uses and the date from which any such restriction should apply;

4. That the Secretariat should make available to the Parties each year a consolidated list of laboratory and analytical uses that the Parties have agreed should no longer be eligible for production and consumption of controlled ozone-depleting substances under the global exemption;
5. That any decision taken to remove the global exemption should not prevent a Party from nominating a specific use for an exemption under the essential uses procedure set out in decision IV/25.

B.9 Decision XI/15: Global exemption for laboratory and analytical uses

To eliminate the following uses from the global exemption for laboratory and analytical uses for controlled substances, approved in decision X/19, from the year 2002:

(a) Testing of oil, grease and total petroleum hydrocarbons in water;

(b) Testing of tar in road-paving materials; and

(c) Forensic finger-printing.

B.10 Decision VII/28. Essential use nominations for controlled substances for 1996 and beyond

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Technical Options Committees pursuant to Decision IV/25 of the Fourth Meeting of the Parties;

2. That, for 1996, 1997, 1998, 1999, 2000 and 2001 for Parties not operating under paragraph 1 of Article 5 of the Protocol, levels of production and consumption necessary to satisfy essential uses of CFC-11, CFC-12, CFC-113, CFC-114 and methyl chloroform are authorised as specified in Annex VI to the report of the Seventh Meeting of the Parties, for metered-dose inhalers (MDIs) for asthma and chronic obstructive pulmonary disease, nasal dexamethasone, and specific cleaning, bonding and surface activation applications in rocket motor manufacturing for the United States Space Shuttle and Titan, subject to the following conditions:

(a) The Technology and Economic Assessment Panel will review, annually, the quantity of controlled substances authorised and submit a report to the Meeting of the Parties in that year;

(b) The Technology and Economic Assessment Panel will review, biennially, whether the applications for which exemption was granted still meets the essential-use criteria and submit a report, through the Secretariat, to the Meeting of the Parties in the year in which the review is made;

(c) The Parties granted essential use exemptions will reallocate, as decided by the Parties, to other uses the exemptions granted or destroy any surplus ozone depleting substances authorised for essential use but subsequently rendered unnecessary a result of technical progress and market adjustments;

3. To urge the Parties to collate, co-ordinate and evaluate the individual company nominations for future years before submitting these nominations to the Secretariat.

B.11 Decision VIII/9. Essential use nominations for Parties not operating under Article 5 for controlled substances for 1997 through 2002

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Technical Options Committees pursuant to Decision IV/25 of the Fourth Meeting of the Parties and Decisions VII/28 and VII/34 of the Seventh Meeting of the Parties;
2. That the levels of production and consumption necessary to satisfy essential uses of CFC-11, CFC-12, CFC-113 and CFC-114, for metered-dose inhalers (MDIs) for asthma and chronic obstructive pulmonary diseases and nasal dexamethasone, and halon 2402 for fire protection are authorised as specified in annex II to this report, subject to the conditions established by the Seventh Meeting of the Parties in paragraph 2 of its Decision VII/23;


4. That for 1998, for Parties not operating under Article 5 of the Protocol, production and consumption necessary to satisfy essential uses of controlled substances in Annexes a and B of the protocol only for laboratory and analytical uses, as listed in annex IV to the report of the Seventh Meeting of the Parties, are authorised and subject to the conditions applied to exemption for laboratory and analytical uses as contained in annex II to the report of the Sixth Meeting of the Parties;

5. To permit the transfer of essential use authorisations for MDIs for 1997 between New Zealand and Australia on a one-time basis only;

6. To request the Technology and Economic Assessment Panel and its relevant Technical Options Committee to investigate the implications of allowing greater flexibility in the transfer of essential use authorisations between Parties;

7. To request the Technology and Economic Assessment Panel and its relevant Technical Options Committee to review and report, by 30 April 1997, on the implications of allowing the production of CFCs for medical applications on a periodic "campaign basis" to satisfy estimated future needs, rather than producing small quantities in each year. Consideration should be given in particular to the economic implications of such an allowance;

8. To revise the timetables in Decision IV/25, as modified by Decision V/18, for nominations for production and consumption exemptions for 1998 and subsequent years, as follows: to set 31 January of each year as the last date for nominations for decisions to be taken in that year for production or consumption in any subsequent year; and to request the Technology and Economic Assessment Panel and its relevant Technical Options Committees to develop recommendations on the nominations and submit their report though the Secretariat by 30 April of that year;

9. To approve the format for reporting quantities and uses of ozone depleting substances produced and consumed for essential uses as set out in annex IV to the report of the Eighth Meeting and beginning in 1998 to request each of the Parties that have had essential use exemptions granted for previous years, to submit their report in the approved format by 31 January of each year;

10. To allow the Secretariat, in consultation with the Technology and Economic Assessment Panel, to authorise, in an emergency situation, if possible by transfer of essential use exemptions, consumption of quantities not exceeding 20 tonnes of ODS for essential uses on application by the Party prior to the next scheduled Meeting of the Parties. The Secretariat should present this information to the next Meeting of the Parties for review and appropriate action by the Parties.
B.12 Decision VIII/10. Actions by Parties not operating under Article 5 to promote industry's participation on a smooth and efficient transition away from CFC-based MDIs

1. That Parties not operating under Article 5 will request companies applying for MDI essential-use exemptions to demonstrate ongoing research and development of alternatives to CFC MDIs with all due diligence and/or collaborate with other companies in such efforts and, with each future request, to report in confidence to the nominating Party whether and to what extent resources are deployed to this end and progress is being made on such research and development, and what licence applications if any have been submitted to health authorities for non-CFC alternatives;

2. That Parties not operating under Article 5 will request companies applying for MDI essential-use exemptions to demonstrate that they are undertaking individual or collaborative industry efforts, in consultation with the medical community, to educate health-care professionals and patients about other treatment options and the transition to non-CFC alternatives;

3. That Parties not operating under Article 5 will request companies applying for MDI essential-use exemptions to demonstrate that they, or companies distributing or selling their product, are differentiating the packaging of the company's non CFC MDIs from its CFC MDIs and are applying other appropriate marketing strategies, in consultation with the medical community, to encourage doctor and patient acceptance of the company's non-CFC alternatives subject to health and product-safety considerations;

4. That Parties not operating under Article 5 will request companies manufacturing, distributing or selling CFC MDIs and non-CFC alternatives not to engage in false or misleading advertising targeted at non-CFC alternatives or CFC MDIs;

5. That Parties not operating under Article 5 will request companies applying for MDI essential-use exemptions to ensure that participation in regulatory proceedings is conducted with a view toward legitimate environmental, health and safety concerns;

6. That Parties not operating under Article 5 will request companies manufacturing CFC MDIs to take all economically feasible steps to minimise CFC emissions during the manufacture of MDIs;

7. That Parties not operating under Article 5 will request companies manufacturing, distributing or selling CFC MDIs to dispose of expired, defective, and returned MDIs containing CFCs in a manner that minimises CFC emissions;

8. That Parties not operating under Article 5 will request companies manufacturing CFC MDIs to review annually CFC requirements and current MDI market forecasts, and notify national regulatory authorities if such forecasts will result in surplus CFCs obtained under essential use exemptions;

9. That Parties not operating under Article 5 will request companies applying for MDI essential use exemptions to provide information of the steps that are being taken to provide a continuity of supply of asthma and chronic obstructive pulmonary disease (COPD) treatments (including CFC MDIs) to importing countries;

10. That Parties not operating under Article 5 will request companies applying for MDI essential use exemptions to provide information that demonstrates the steps being taken to assist the
company’s MDI manufacturing facilities in Parties operating under Article 5 and countries with economies in transition in upgrading the technology and capital equipment needed for manufacturing non-CFC asthma and chronic obstructive pulmonary disease (COPD) treatments;

11. To request the Technology and Economic Assessment Panel to reflect paragraphs I through 10 above in a revised version of the Handbook on Essential Use Nominations.

B.13 Decision VIII/11. Measures to facilitate a transition by a Party not operating under Article 5 from CFC-based MDIs

The Parties note that a transition is occurring from the use of CFC-based MDIs to non-CFC treatments for asthma and chronic obstructive pulmonary disease. In order to ensure a smooth and efficient transition, and protect the health and safety of patients, Parties not operating under Article 5 are encouraged:

1. To promote co-ordination between national environmental and health authorities on the environmental, health and safety implications of any proposed decisions on essential-use nominations and MDI transition policies;

2. To request their national authorities to expedite review of marketing/licensing/pricing applications of non-CFC treatments of asthma and chronic obstructive pulmonary disease, provided that such expedited review does not compromise patient health and safety;

3. To request their national authorities to review the terms for public MDI procurement and reimbursement, so that purchasing policies do not discriminate against non-CFC alternatives.

B.14 Decision VIII/12. Information gathering on a transition to non CFC treatments for asthma and chronic obstructive pulmonary disease for Parties not operating under Article 5

1. To note with appreciation the work done by the Technology and Economic Assessment Panel and its Technical Options Committee pursuant to Decision IV/25 of the Fourth Meeting of the Parties and Decision VII/28 of the Seventh Meeting of the Parties;

2. To note with appreciation that one new non-CFC-based MDI for one active ingredient has now entered the market in some countries, and that others are anticipated over the next one to three years. Other non-CFC treatments and devices already provide a suitable alternative for many patients in some Parties not operating under Article 5;

3. To request Parties not operating under Article 5 that have developed a national transition strategy to report to the panel and its relevant Technical Options Committee on the details of that national transition strategy for non-CFC treatments of asthma and chronic obstructive pulmonary disease in time for meetings of the Technical Options Committee, beginning in 1997;

4. To request the Technology and Economic Assessment Panel and its relevant Technical Options Committee to provide an interim report on progress in the development and implementation of national transition treatments of asthma and chronic obstructive pulmonary disease (COPD) and report to the Open-Ended Working Group in preparation for the Ninth Meeting of the Parties;

5. To request the Technology and Economic Assessment Panel to further examine and provide a progress report to the Ninth Meeting of the Parties and a final report to the Tenth Meeting
of the Parties on issues surrounding a transition to non-CFC treatments of asthma and chronic obstructive pulmonary disease in Parties not operating under Article 5 that is fully protective of public health. In so doing, the Technology and Economic Assessment Panel should consult with international bodies, such as the World Health Organisation and other international bodies, and other institutions representing health-care professionals, patient-advocacy groups and private industry, and with national bodies and Governments. The Technology and Economic Assessment Panel should consider:

(a) In the context of a transition phase, how decisions taken within the Montreal Protocol framework and national strategies might complement each other;

(b) The impact on the right and ability of patients in Parties operating under Article 5, in countries with economies in transition, in Parties not operating under Article 5 with large disadvantaged communities and in importing countries to receive CFC-based MDIs where medically acceptable and affordable alternatives are not available due to reductions in essential-use exemptions in Parties not operating under Article 5 for CFC-based MDIs;

(c) The influence of potential transferable essential use exemptions as well as existing and potential trade restrictions by individual countries on a smooth transition and access to affordable treatment options;

(d) The international markets and fluidity of trade in CFC-based MDIs as well as alternative treatments for asthma and chronic obstructive pulmonary disease;

(e) The implications for patient subgroups which may have continuing compelling medical needs after a virtual phase-out;

(f) The range of regulatory and non-regulatory incentives for, and impediments to, research and development of alternative treatments for asthma and chronic obstructive pulmonary disease and market penetration of alternative treatments for asthma and chronic obstructive pulmonary disease;

(g) The degree to which dry powder inhalers (DPIs) and other treatments options may be considered medically acceptable and affordable alternatives for CFC-based MDIs in consultation with the above bodies, as a result, the factors which may influence their ability to act as substitutes in different countries;

(h) The relative implications for the phase-out of ozone-depleting substances of different policy options that facilitate the transition to non-CFC treatments;

(i) Steps that could be taken to facilitate access to affordable non-CFC treatments.

**B.15 Decision IX/19. Metered-dose inhalers (MDIs)**

1. To note with appreciation the interim report of the Technology and Economic Assessment Panel (TEAP) pursuant to decision VIII/12;

2. To request the Technology and Economic Assessment Panel to continue its work and submit the final report to the Tenth Meeting of the Parties, through the Open-ended Working Group, taking into account the approach indicated in paragraph 5 of decision VIII/12 and the comments made during the fifteenth and sixteenth meetings of the Open-ended Working Group and the Ninth Meeting of the Parties;

3. To note the expectation of TEAP and its relevant Technical Options Committee that it
remains possible that the major part of the MDI transition may occur in non-Article 5 countries by the year 2000 and there will be minimal need for CFCs for metered-dose inhalers by 2005, however, at this point in time there are still many variables and an exact time-scale is not possible to predict with certainty;

4. To note the concerns of some non-Article 5 Parties that they may not be able to convert as soon as they would like unless their independent MDI manufacturers are able to license non-CFC technologies;

5. To require non-Article 5 Parties submitting essential-use nominations for CFCs for MDIs for the treatment of asthma and chronic obstructive pulmonary disease (COPD) to present to the Ozone Secretariat an initial national or regional transition strategy by 31 January 1999 for circulation to all Parties. Where possible, non-Article 5 Parties are encouraged to develop and submit to the Secretariat an initial transition strategy by 31 January 1998. In preparing a transition strategy, non-Article 5 Parties should take into consideration the availability and price of treatments for asthma and COPD in countries currently importing CFC MDIs.

B.16 Decision IX/20. Transfer of essential-use authorisations for CFCs for MDIs

1. That all transfers of essential-use authorizations for CFCs for MDIs be reviewed on a case-by-case basis at Meetings of the Parties for approval;

2. Notwithstanding paragraph 1 of the present decision, to allow the Secretariat, in consultation with the Technology and Economic Assessment Panel, to authorize a Party, in an emergency situation, to transfer some or all of its authorized levels of CFCs for essential uses in MDIs to another Party, provided that:

   (a) The transfer applies only up to the maximum level that has previously been authorized for the calendar year in which the next Meeting of the Parties is to be held;

   (b) Both Parties involved agree to the transfer;

   (c) The aggregate annual level of authorizations for all Parties for essential uses of MDIs does not increase as a result of the transfer;

   (d) The transfer or receipt is reported by each Party involved on the essential-use quantity-accounting format approved by the Eighth Meeting of the Parties by paragraph 9 of decision VIII/9.

B.17 Decision XII/2. Measures to facilitate the transition to chlorofluorocarbon-free metered-dose inhalers

1. For the purposes of this decision, "chlorofluorocarbon metered-dose inhaler product" means a chlorofluorocarbon-containing metered-dose inhaler of a particular brand name or company, active ingredient(s) and strength;

2. That any chlorofluorocarbon metered-dose inhaler product approved after 31 December 2000 for treatment of asthma and/or chronic obstructive pulmonary disease in a non-Article 5(l) Party is not an essential use unless the product meets the criteria set out in paragraph 1(a) of decision IV/25;

3. With respect to any chlorofluorocarbon metered-dose inhaler active ingredient or category of products that a Party has determined to be non-essential and thereby not authorized for domestic use, to request:
(a) The Party that has made the determination to notify the Secretariat;

(b) The Secretariat to maintain such a list on its Web site;

(c) Each nominating Party to reduce accordingly the volume of chlorofluorocarbons it requests and licenses;

4. To encourage each Party to urge each metered-dose inhaler company within its territory to diligently seek approval for the company's chlorofluorocarbon-free alternatives in its domestic and export markets, and to require each Party to provide a general report on such efforts to the Secretariat by 31 January 2002 and each year thereafter;

5. To agree that each non-Article 5 Party should, if it has not already done so:

(a) Develop a national or regional transition strategy based on economically and technically feasible alternatives or substitutes that it deems acceptable from the standpoint of environment and health and that includes effective criteria and measures for determining when chlorofluorocarbon metered-dose inhaler product(s) is/are no longer essential;

(b) Submit the text of any such strategy to the Secretariat by 31 January 2002;

(c) Report to the Secretariat by 31 January each year thereafter on progress made on its transition to chlorofluorocarbon-free metered-dose inhalers;

6. To encourage each Article 5(l) Party to:

(a) Develop a national or regional transition strategy based on economically and technically feasible alternatives or substitutes that it deems acceptable from the standpoint of environment and health and that includes effective criteria and measures for determining when chlorofluorocarbon metered-dose inhaler product(s) can be replaced with chlorofluorocarbon-free alternatives;

(b) Submit the text of any such a strategy to the Secretariat by 31 January 2005;

(c) Report to the Secretariat by 31 January each year thereafter on progress made on its transition to chlorofluorocarbon-free metered-dose inhalers;

7. To request the Executive Committee of the Multilateral Fund to consider providing technical, financial and other assistance to Article 5(l) Parties to facilitate the development of metered-dose inhaler transition strategies and the implementation of approved activities contained therein, and to invite the Global Environment Facility to consider providing the same assistance to those eligible countries with economies in transition;

8. To decide that, as a means of avoiding unnecessary production of new chlorofluorocarbons, and provided that the conditions set out in paragraphs (a) - (d) of decision IX/20 are met, a Party may allow a metered-dose inhaler company to transfer:

(a) All or part of its essential use authorization to another existing metered-dose inhaler company; or

(b) Chlorofluorocarbons to another metered-dose inhaler company provided that the transfer complies with national/regional licence or other authorization requirements;

9. To request the Technology and Economic Assessment Panel to summarize and review by 15
May each year the information submitted to the Secretariat;

10. To modify as necessary the Handbook for Essential Use Nominations to take account of the requirements contained in this decision as they pertain to non-Article 5(l) Parties;

11. To request the Technology and Economic Assessment Panel to consider and report to the next Meeting of the Parties on issues related to the campaign production of chlorofluorocarbons for chlorofluorocarbon metered-dose inhalers.

**B.18 Decision XIII/9. Metered-dose inhaler (MDI) production**

To request the Executive Committee to prepare guidelines for the presentation of MDI projects involving the preparation of strategies and investment projects that would enable the move to CFC-free production of MDIs in Article 5 countries, and enable them to meet their obligations under the Montreal Protocol.

**B.19 Decision XIII/10. Further study of campaign production of CFCs for metered-dose inhalers (MDIs)**

*Noting* that the Technology and Economic Assessment Panel and Technical Options Committee review recommended that just-in-time production of CFCs for the manufacture of metered-dose inhalers is the best approach to protect the health of patients,

*Noting, however*, the possibility that just-in-time production of CFCs for the manufacture of CFC-based MDIs may not be available through to the end of the transition, and that the end of just-in-time production could come unexpectedly,

1. To note with appreciation the work of the Technology and Economic Assessment Panel and its Technical Options Committees in studying the issue of campaign production of CFCs for manufacturing CFC-based MDIs;

2. To request the Technology and Economic Assessment Panel and Technical Options Committees to analyse the current essential-use decisions and procedures to identify if changes are needed to facilitate expedient authorization for campaign production, including information needed for the review and authorization of nominations for campaign production quantities, the contingencies for under- and over-estimation of the quantities needed for a campaign production, the timing of the campaign production vis-à-vis export and import of those quantities, the oversight and reporting on the use of campaign production quantities, and the flexibility in ensuring that the campaign production is used only in the manufacture of MDIs for the treatment of asthma and chronic obstructive pulmonary disease or that any excess is destroyed;

3. To request the Technology and Economic Assessment Panel to present its findings to the Open-ended Working Group in 2002;

4. To request the Technology and Economic Assessment Panel to continue to monitor and report on the timing of the likely need for campaign production.
**Decision XIV/5. Global database and assessment to determine appropriate measures to complete the transition from chlorofluorocarbon metered-dose inhalers**

Noting that while the transition to chlorofluorocarbon-free (CFC-free) alternative treatments for asthma and chronic obstructive pulmonary disease (COPD) depends largely on non-Article 5(1) Parties adopting effective transition strategies and CFC metered-dose inhaler manufacturers diligently developing, seeking approval for, and launching CFC-free metered-dose inhalers and dry-powder inhalers;

Noting with concern the slow transition to CFC-free metered-dose inhalers in some Parties, and the need for affordable and available alternatives in Parties operating under Article 5(1);

Recognizing the desirability of a more transparent presentation of data to assist Parties in better understanding essential use CFC volumes and gauging progress on, and impediments to, the transition;

1. To request each Party or regional economic integration organization to submit available information to the Ozone Secretariat by 28 February 2003 and annual updates thereafter the following information concerning inhaler treatments for asthma and COPD that contain CFCs or that do not contain CFCs:

   (a) CFC and non-CFC metered-dose inhalers and dry-powder inhalers: sold or distributed within the Party, by active ingredient, brand/manufacturer, and source (import or domestic production);

   (b) CFC and non-CFC metered-dose inhalers and dry-powder inhalers: produced within the Party for export to other Parties, by active ingredient, brand/manufacturer, source and importing Party;

   (c) Non-CFC metered-dose inhalers and dry-powder inhalers: date approved, authorized for marketing, and/or launched in the territory of the Party;

2. To request the Technology and Economic Assessment Panel to take into account information submitted pursuant to paragraph 1 and other available information in its annual assessment, and to request the Parties to pay due consideration to this information when reviewing their national transition strategies.

**Decision XV/5. Promoting the closure of essential-use nominations for metered-dose inhalers**

1. That the present decision shall not affect the operation of paragraph 10 of decision VIII/9 relating to the authorization of a quantity of CFCs in an emergency situation;

2. To request that Parties not operating under paragraph 1 of Article 5, when submitting their nominations for essential-use exemptions for CFCs for metered-dose inhalers, specify, for each nominated use, the active ingredients, the intended market for sale or distribution and the quantity of CFCs required;

3. To request the Technology and Economic Assessment Panel and its Technical Options Committee to make recommendations on nominations for essential-use exemptions for CFCs for metered-dose inhalers from Parties not operating under paragraph 1 of Article 5 with reference to the active ingredient of the metered-dose inhalers in which the CFCs will be used and the intended market for sale or distribution and any national transition strategy
covering that intended market which has been submitted according to decision XII/2 or decision IX/19;

4. That no quantity of CFCs for essential uses shall be authorized after the commencement of the Seventeenth Meeting of the Parties if the nominating Party not operating under paragraph 1 of Article 5 has not submitted to the Ozone Secretariat, in time for consideration by the Parties at the twenty-fifth meeting of the Open-ended Working Group, a plan of action regarding the phase-out of the domestic use of CFC-containing metered-dose inhalers where the sole active ingredient is salbutamol;

5. That the plans of action referred to in paragraph 4 above must include:

(a) A specific date by which time the Party will cease making nominations for essential-use exemptions for CFCs for metered-dose inhalers where the sole active ingredient is salbutamol and where the metered-dose inhalers are expected to be sold or distributed on the market of any Party not operating under paragraph 1 of Article 5;

(b) The specific measures and actions sufficient to deliver the phase-out;

(c) Where appropriate, the actions or measures needed to ensure continuing access to or supply of CFC-containing metered-dose inhalers by Parties operating under paragraph 1 of Article 5;

6. To request each Party not operating under paragraph 1 of Article 5 to submit to the Ozone Secretariat as soon as practicable for that Party specific dates by which time it will cease making nominations for essential-use exemptions for CFCs for metered-dose inhalers where the active ingredient is not solely salbutamol and where the metered-dose inhalers are expected to be sold or distributed on the market of any Party not operating under paragraph 1 of Article 5;

7. To request the Technology and Economic Assessment Panel to report, in time for the twenty-fourth meeting of the Open-ended Working Group, on the potential impacts of the phase-out of CFCs in Parties not operating under paragraph 1 of Article 5 on the availability of affordable inhaled therapy in Parties operating under paragraph 1 of Article 5;

8. To request the Ozone Secretariat to post on its website all data submitted pursuant to decision XIV/5 that are designated non-confidential by the submitting Party;

9. To request the Technology and Economic Assessment Panel to modify the Handbook on Essential Use Nominations to reflect the present decision.

B.22 Decision XVI/12. Essential-use nominations for non-Article 5 Parties for controlled substances for 2005 and 2006

1. To authorize the levels of production and consumption necessary to satisfy essential uses of CFCs for metered-dose inhalers for asthma and chronic obstructive pulmonary diseases as specified in the annex to this decision, subject to the conditions established by the Meeting of the Parties in paragraph 2 of its decision VII/28 and subject to a second review of the 2006 levels consistent with decision XV/5;

2. To urge the Technology and Economic Assessment Panel to specify in the Handbook on Essential Use Nominations that a nominating Party may submit in its nomination data aggregated by region and product group for CFC-containing metered-dose inhalers intended for sale in Parties operating under paragraph 1 of Article 5 when more specific data are not available;
3. That, in light of the fact that Aerosol Technical Options Committee’s recommendations for future essential-use exemptions are based on past stock level information, Parties, when preparing essential use nominations for CFCs, should give due consideration to existing stocks, whether owned or agreed to be acquired from a metered-dose inhaler manufacturer, of banked or recycled controlled substances as described in paragraph 1(b) of decision IV/25, with the objective of maintaining no more than one year’s operational supply.

B.23 Decision XVII/5: Essential-use nominations for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2006 and 2007

Noting with appreciation the work done by the Technology and Economic Assessment Panel and its Medical Technical Options Committee,

Noting with appreciation the progress made since the adoption of decision XV/5 by Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol in establishing a certain date by which they will cease submitting nominations for metered-dose inhalers where the sole active ingredient is salbutamol;

Recalling paragraph 6 of decision XV/5 relating to the phase-out of chlorofluorocarbons for metered-dose inhalers where the active ingredient is not solely salbutamol,

1. To authorize the levels of production and consumption for 2006 and 2007 necessary to satisfy essential uses of chlorofluorocarbons for metered-dose inhalers for asthma and chronic obstructive pulmonary disease as specified in the annex to the present decision;

2. That Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol, when licensing, authorizing, or allocating essential-use exemptions for chlorofluorocarbons for a manufacturer, shall take into account pre- and post-1996 stocks of controlled substances as described in paragraph 1(b) of decision IV/25, such that no more than a one-year operational supply is maintained by that manufacturer;

3. With reference to paragraph 6 of decision XV/5, to request that Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol submit a date to the Ozone Secretariat prior to the Eighteenth Meeting of the Parties by which time a regulation or regulations to determine the non-essentiality of the vast majority of chlorofluorocarbons for metered-dose inhalers where the active ingredient is not solely salbutamol will have been proposed;

B.24 Decision XVII/14: Difficulties faced by some Parties operating under paragraph 1 of Article 5 of the Montreal Protocol with respect to chlorofluorocarbons used in the manufacture of metered-dose inhalers

Acknowledging that Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol have phased out chlorofluorocarbons but under specific conditions, can apply for essential-use exemption for the consumption of chlorofluorocarbons in the manufacture of metered-dose inhalers as specified by the Meeting of the Parties,

Concerned that Parties operating under paragraph 1 of Article 5 of the Protocol which consume chlorofluorocarbons for the manufacture of metered-dose inhalers may find it difficult to phase out these substances without incurring economic losses to their countries,

Calling upon the parent pharmaceutical companies to accelerate the transfer of non-chlorofluorocarbon technologies to their joint venture partners in developing countries,

Noting the need for further work to be undertaken to assemble and document the new non-
ozone-depleting substances methods of technology for metered-dose inhalers that would allow elimination of further uses of chlorofluorocarbons,

*Noting with concern* that there is a serious risk that, for some Parties operating under paragraph 1 of Article 5, consumption levels in 2007 of chlorofluorocarbons for metered-dose inhaler uses may exceed the allowable amounts,

*Aware* of the critical need by Parties operating under paragraph 1 of Article 5 for the consumption of metered-dose inhalers for protecting human health,

*Recognizing* also the difficulties that may be faced by Parties operating under paragraph 1 of Article 5 in obtaining sufficient supply of Annex A, group I (chlorofluorocarbons) controlled substances during the period 2007–2009,

1. To consider at the Eighteenth Meeting of the Parties a possible decision which would address the difficulties that some Parties operating under paragraph 1 of Article 5 may face in relation to metered-dose inhalers;

2. To request the Executive Committee of the Multilateral Fund to examine situations such as these and consider options that might assist this potential situation of non-compliance;

3. To request the Executive Committee to consider appropriate regional workshops to create awareness and educate stakeholders, including doctors and patients, on alternative metered-dose inhalers and on the elimination of chlorofluorocarbons in metered-dose inhaler uses and technical assistance to Article 5 Parties to phase out this use;

4. To request the Open-ended Working Group at its twenty-sixth meeting to consider the issue;

**B.25 Decision XVIII/7: Essential-use exemptions for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2007 and 2008**

*Noting* with appreciation the work done by the Technology and Economic Assessment Panel and its Medical Technical Options Committee,

*Taking* into account the Technology and Economic Assessment Panel’s expectation that production of metered-dose inhalers containing chlorofluorocarbons should cease by the end of 2009 and, based on its analysis and monitoring of the transition to chlorofluorocarbon-free treatments of asthma and chronic obstructive pulmonary disease over the last decade, the Panel’s assessment that global phase-out of chlorofluorocarbon -based metered-dose inhalers will be achievable by 2010,

*Considering* the Technology and Economic Assessment Panel's conclusion that technically satisfactory alternatives to chlorofluorocarbon-based metered-dose inhalers are available for short-acting beta-agonists and other therapeutic categories for asthma and chronic obstructive pulmonary disease,

*Mindful* that, according to decision IV/25, chlorofluorocarbon use for metered-dose inhalers shall not qualify as essential if technically and economically feasible alternatives or substitutes are available that are acceptable from the standpoint of environment and health,

*Welcoming* the fact that the United States has demonstrated its commitment in its domestic process to allocate only the minimal amount necessary to protect public health, having issued a proposed regulation that would allocate 125.3 tons for 2007,
Mindful that paragraph 8 of decision XII/2 allows the transfer of chlorofluorocarbons between metered-dose inhaler companies,

1. To authorize the levels of production and consumption for 2007 and 2008 necessary to satisfy essential uses of chlorofluorocarbons for the production of metered-dose inhalers for asthma and chronic obstructive pulmonary disease specified in annex III to the present report;

2. That Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol, when licensing, authorizing, or allocating essential-use exemptions for chlorofluorocarbons for a manufacturer of metered-dose inhalers for asthma and chronic obstructive pulmonary diseases, shall take into account pre- and post-1996 stocks of controlled substances as described in paragraph 1 (b) of decision IV/25, such that no more than a one-year operational supply is maintained by the manufacturer;

3. That Parties not operating under Article 5 will request companies applying for metered-dose inhaler essential use exemptions to demonstrate that they are making efforts, with all due diligence, on research and development with respect to chlorofluorocarbon-free alternatives to their products and are diligently seeking approval of their chlorofluorocarbon-free alternatives in their domestic and export markets aimed at transitioning those markets away from the chlorofluorocarbon products;

B.26 Decision XVIII/16: Difficulties faced by some Article 5 Parties manufacturing metered-dose inhalers which use chlorofluorocarbons

Recognizing that Parties operating under paragraph 1 of Article 5 must reduce consumption of Annex A, group I, controlled substances (chlorofluorocarbons) by 85 per cent of their baseline by 2007 and complete the phase-out of those substances by 1 January 2010, including chlorofluorocarbons used in metered-dose inhalers for the treatment of asthma and chronic obstructive pulmonary disease,

Bearing in mind that, according to paragraph 7 of decision IV/25, essential-use controls will not be applicable to Parties operating under paragraph 1 of Article 5 until the phase-out dates applicable to those Parties,

Recognizing the potential uncertainty of supplies of pharmaceutical grade chlorofluorocarbons in the near future and the impact on people’s health and local businesses if national manufacturing plants which depend on imports of those substances cannot predict their availability,

Aware that the phase-out of chlorofluorocarbon-based metered-dose inhalers in Parties not operating under paragraph 1 of Article 5 is likely to be complete by the phase-out deadline for Parties operating under Article 5 and that most of the metered-dose inhalers used by patients in many Parties operating under paragraph 1 of Article 5 are imported from Parties not operating under paragraph 1 of Article 5,

Acknowledging that some Parties operating under paragraph 1 of Article 5 have adopted metered-dose inhaler transition strategies, as encouraged by decision XII/2, but noting that most Parties operating under paragraph 1 of Article 5 have yet to put in place national or regional transition strategies and that Parties that produce metered-dose inhalers will be unable to finalize such strategies unless technology conversion is included in their national plans,

Understanding, therefore, that there is a need for further measures to facilitate the transition to
non-chlorofluorocarbon treatments for asthma and obstructive pulmonary disease in Parties operating under paragraph 1 of Article 5,

*Mindful* that in some cases a regional approach to transition may be the most efficient,

*Noting* that Parties not operating under paragraph 1 of article 5 have made substantial progress in replacing chlorofluorocarbon-based metered-dose inhalers with alternative products but that at the present time still require a limited amount of pharmaceutical grade chlorofluorocarbons to produce metered-dose inhalers, as demonstrated by current essential-use exemption requests granted by the Parties,

*Taking into account* that decision XVII/14 calls for the Eighteenth Meeting of the Parties to consider taking a decision addressing the difficulties faced by Parties operating under paragraph 1 of Article 5 on metered-dose inhaler transition,

1. To request the Executive Committee of the Multilateral Fund for the Implementation of the Montreal Protocol to consider as a matter of urgency the funding of projects in relation to those Parties operating under paragraph 1 of Article 5 that experience difficulties due to high consumption of chlorofluorocarbons for manufacturing metered-dose inhalers, in order to facilitate the transition from chlorofluorocarbon-based metered-dose inhalers;

2. To request the Executive Committee to consider within the context of the existing Multilateral Fund guidelines to review its decision 17/7 with regard to the existing cut-off date for consideration of metered dose inhaler conversion projects consistent with the reality of the pace of technological advances in the metered-dose inhaler sector;

3. To request the Implementation Committee under the Non-compliance Procedure of the Montreal Protocol to consider all possible options on how to address the potential non-compliance difficulties of some Parties operating under paragraph 1 of Article 5 resulting from their high proportion of chlorofluorocarbon consumption in the metered-dose inhaler sector;

4. To further request the Implementation Committee to give special consideration to the situation of such Parties, particularly in the context of paragraph 4 of the non-compliance procedure of the Protocol, in the light of information received from the Parties concerned and having due regard to health considerations;

5. To consider again the matter referred to in paragraphs 3 and 4 at the twentieth Meeting of the Parties in 2008;

6. To request the Executive Committee to consider including on the agenda of the United Nations Environment Programme thematic regional workshops, information to clarify the steps required to advance the transition from chlorofluorocarbon metered-dose inhalers;

7. To request each Party not operating under paragraph 1 of Article 5 receiving essential-use exemptions for the production or import of chlorofluorocarbons to manufacture metered-dose inhalers for export to Parties operating under paragraph 1 of Article 5 to submit to each importing Party a detailed export manufacturing transition plan for each manufacturer where the exports of an active ingredient to that Party exceed 10 metric tonnes, specifying the actions that each manufacturer is taking and will take to transition its exports to chlorofluorocarbon-free metered-dose inhalers as expeditiously as possible in a manner that does not put patients at risk;

8. That each manufacturer’s export manufacturing transition plans should include specific details
for each of the manufacturer’s export markets and for each metered-dose inhaler by active ingredient concerning:

(a) Timing of submission to the health authority of marketing applications for chlorofluorocarbon-free alternatives, expected approval and launch of such alternatives and withdrawal of associated chlorofluorocarbon product or products;

(b) Indicative information on facilitative pricing, licensing and/or technology transfer arrangements under consideration;

(c) Contribution to, and participation in, programmes for educating health care professionals, government health authorities and patients about the transition to chlorofluorocarbon-free treatments for asthma and chronic obstructive pulmonary disease;

9. Consistent with decision IV/25 and paragraph 4 of decision XII/2, to request each Party referred to in paragraph 7 of the present decision, when deciding whether to nominate essential-use volumes for and/or grant essential-use licenses to a manufacturer, to take into account the manufacturer’s efforts to implement its export manufacturing transition plan and its contribution to transition towards chlorofluorocarbon-free metered-dose inhalers;

10. To request each Party referred to in paragraph 7 to submit each year to the Technology and Economic Assessment Panel, as part of the Party’s essential-use nomination, a report summarizing the export manufacturing transition plans submitted, taking care to protect any confidential information;

11. To request the Technology and Economic Assessment Panel to consider such reports in its assessment of each Party’s essential-use nominations;

12. To request the Technology and Economic Assessment Panel to assess and report on progress at the twenty-seventh meeting Open-ended Working Group and to report to the Nineteenth Meeting of the Parties on the need for, feasibility of, optimal timing of, and recommended quantities for a limited campaign production of chlorofluorocarbons exclusively for metered-dose inhalers in both Parties operating under paragraph 1 of Article 5 and Parties not operating under paragraph 1 of Article 5.

B.27 Decision XIX/13: Essential-use nominations for Parties not operating under paragraph 1 of Article 5 for controlled substances for 2008 and 2009

Noting with appreciation the work done by the Technology and Economic Assessment Panel and its Medical Technical Options Committee,

Mindful that, according to decision IV/25, the use of chlorofluorocarbons (CFCs) for metered-dose inhalers does not qualify as an essential use if technically and economically feasible alternatives or substitutes are available that are acceptable from the standpoint of environment and health,

Noting the Technology and Economic Assessment Panel's conclusion that technically satisfactory alternatives to chlorofluorocarbon-based metered-dose inhalers are available for short-acting beta-agonists and other therapeutic categories for asthma and chronic obstructive pulmonary disease,

Mindful that paragraph 8 of decision XII/2 allows the transfer of CFCs between metered-dose inhaler companies,
Welcoming the continued progress in several Parties not operating under paragraph 1 of Article 5 in reducing their reliance on CFC-containing metered-dose inhalers as alternatives are developed, receive regulatory approval and are marketed for sale,

1. To authorize the levels of production and consumption for 2008 and 2009 necessary to satisfy essential uses of CFCs for metered-dose inhalers for asthma and chronic obstructive pulmonary disease specified in the annexes to the present decision;

2. That Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol, when licensing, authorizing or allocating essential-use exemptions for a manufacturer of metered-dose inhalers, shall ensure, in accordance with paragraph 1 (b) of decision IV/25, that pre- and post-1996 stocks of controlled substances are taken into account such that no more than a one-year operational supply is maintained by the manufacturer;

3. That Parties not operating under paragraph 1 of Article 5 of the Montreal Protocol will request each company, consistent with paragraph 1 of decision VIII/10, to notify the relevant authority, for each metered-dose inhaler product for which the production of CFCs is requested, of:
   (a) The company’s commitment to the reformulation of the concerned products;
   (b) The timetable in which each reformulation process may be completed;
   (c) Evidence that the company is diligently seeking approval of any chlorofluorocarbon-free alternative(s) in its domestic and export markets and transitioning those markets away from its chlorofluorocarbon products;

4. The Parties listed in Annex A to the present decision shall not nominate for the production of essential use volumes of CFCs for the manufacture of metered-dose inhalers in 2010 or any year thereafter.